

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<p>In re Application of</p> <p>Jeffrey L. Cleland et al.</p> <p>Serial No.: 09/273,230</p> <p>Filed: March 18, 1999</p> <p>For: PROTEIN FORMULATION</p>	<p>Group Art Unit: not yet assigned</p> <p>Examiner: not yet assigned</p> <div data-bbox="812 514 1427 764"> <p>CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on</p> <p>July 14, 1999</p> <p><i>Ann Savelli</i></p> <p>Ann Savelli</p> </div>
---	--

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement:

- (a) ☐ accompanies the new patent application submitted herewith. 37 CFR §1.97(a).
- (b) ☐ is filed within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 CFR§1.491.
- (c) ☒ as far as is known to the undersigned, is filed before the mailing date of a first Office action on the merits. Should any fee be due, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$240.00 to cover the cost of this Information Disclosure Statement. Any deficiency or overpayment should be charged or credited to this deposit account.
- (d) ☐ is filed after the first Office Action and more than three months after the application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first, and is accompanied by either the fee (\$240) set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below. Should any

RECEIVED
 JAN 21 2003
 TECH CENTER 1600/2800

fee be due, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$240.00 to cover the cost of this Information Disclosure Statement. Any deficiency or overpayment should be charged or credited to this deposit account. **A duplicate of this sheet is enclosed.**

- (e) ☐ is filed after the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$130) set forth in 37 CFR §1.17(i) **and** a statement as specified in 37 CFR §1.97(e), as checked below. **This document is to be considered as a petition requesting consideration of the information disclosure statement.** The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$130.00 to cover the cost of this Information Disclosure Statement. Any deficiency or overpayment should be charged or credited to this deposit account. **A duplicate of this sheet is enclosed.**

[If either of boxes (d) or (e) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.] The undersigned states that:

- ☐ Each item of information contained in the information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this information disclosure statement.

A list of the patent(s) or publication(s) is set forth on the attached Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith:

☐ each ☐ none ☒ only those listed below:

"Immune Globulin Intravenous (Human) Sandoglobulin" Product Information, Physicians' Desk Reference, pps 2075-2077 (1994).

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 08/615,369, filed March 14, 1996 and relied upon in this application for an earlier filing date under 35 USC §120.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

- ☐ given for only non-English language listed item(s) [Required]
- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

The Examiner is reminded that a "concise explanation of the relevance" of the submitted prior art "may be nothing more than identification of the particular figure or paragraph of the patent or publication which has some relation to the claimed invention," MPEP §609.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR §1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR §1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR §1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR §1.98 and MPEP §609 and the Examiner is respectfully requested to consider the listed references.

Respectfully submitted,

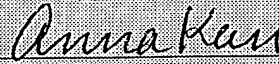
GENENTECH, INC.

Date: July 14, 1999

By: Janet E. Hasak for Wendy Lee
Janet E. Hasak
Reg. No. 28,616

1 DNA Way
So. San Francisco, CA 94080-4990
Phone: (650) 225-1994
Fax: (650) 952-9881

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	Group Art Unit: 1642
Jeffrey L. Cleland et al.	Examiner: G. Bansal
Serial No.: 09/273,230	CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on December 27, 2000  Anna Kan
Filed: March 18, 1999	
For: PROTEIN FORMULATION	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☐ 37 CFR §1.97(b)

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); or
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, or
- before the mailing of the first Office action on the merits; or
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☒ 37 CFR §1.97(c)

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

☐ 37 CFR §1.97(d)

- after the period specified in CFR §1.97(c), and is accompanied by the fee set

TECH CENTER 1600/2900

JAN 21 2003

RECEIVED

forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ 37 CFR §1.97(e) Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ 37 CFR §1.704(d) Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☒ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified). A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. , filed and relied upon in this application for an earlier filing date under 35 USC §120.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-0" (nucleotide) and "BLAST Results B-1 - B-0" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☐ not given
- ☐ given for each listed item
- ☒ given for only non-English language listed items

An English language translation is provided for item 216.
English language abstracts are provided for items 218-223
English language abstracts and claims are provided for items 217 and 224.

- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,

GENENTECH, INC.

By:

Wendy M. Lee

Reg. No. 40,378

Telephone No. (650) 225-1994

Date: December 22, 2000



09157

PATENT TRADEMARK OFFICE

FORM PTO-1449 U.S. Dept. of Commerce Patent and Trademark Office LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)	Atty Docket No. P0998D1	Serial No. 09/273,230
	Applicant Cleland et al.	
	Filing Date 18 Mar 1999	Group 1642

U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
	190	4,935,341	19.06.90	Bargmann et al.		
	191	5,288,477	22.02.94	Bacus, S.		
	192	5,359,046	25.10.94	Capon et al.		
	193	5,401,638	28.03.95	Carney et al.		
	194	5,578,482	26.11.96	Lippman et al.		
	195	5,604,107	18.02.97	Carney et al.		
	196	5,663,144	02.09.97	Greene et al.		
	197	5,705,157	06.01.98	Greene		
	198	5,726,023	10.03.98	Cheever et al.		
	199	5,728,687	17.03.98	Bissery		
	200	5,801,005	01.09.98	Cheever et al.		
	201	5,837,243	17.11.98	Deo et al.		
	202	5,837,523	17.11.98	Greene et al.		
	203	5,846,538	08.12.98	Cheever et al.		
	204	5,869,445	09.02.99	Cheever et al.		
	205	5,876,712	02.03.99	Cheever et al.		
	206	5,877,305	02.03.99	Huston et al.		
	207	5,908,835	01.06.99	Bissery		
	208	5,910,486	08.01.99	Curriel et al.		
	209	5,922,845	13.07.99	Deo et al.		
	210	5,939,531	17.08.99	Wels et al.		
	211	5,977,322	02.11.99	Marks et al.		
	212	6,054,297	25.04.00	Carter et al.		
	213	6,123,939	26.09.00	Shawver et al.		

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
	214	616,812	28.09.94	EPO			
	215	711,565	26.08.98	EPO			
	216	2,761,543B2	04.06.98	JAPAN (TRANSLATION ATTACHED)			
	217	2,895,105B2	24.05.99	JAPAN (ENGLISH ABSTRACT AND CLAIMS)			
	218	3-240498	25.10.91	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	219	5-117165	14.05.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	220	5-170667	09.07.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	221	5-213775	24.08.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	222	5-317084	03.12.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Dept. of Commerce Patent and Trademark Office LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)	Atty Docket No. P0998D1	Serial No. 09/273,230
	Applicant Cleland et al.	
	Filing Date 18 Mar 1999	Group 1642

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes	Translation No
	223	7-59588	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	224	95,006,982B2	JAPAN (ENGLISH ABSTRACT AND CLAIMS)				
	225	WO 92/10573	PCT				
	226	WO 93/12220	PCT				
	227	WO 93/21232	PCT				
	228	WO 93/21319	PCT				
	229	WO 94/10202	PCT				
	230	WO 94/28127	PCT				
	231	WO 95/16051	PCT				
	232	WO 95/17507	PCT				
	233	WO 95/28485	PCT				
	234	WO 96/18409	PCT				
	235	WO 96/30046	PCT				
	236	WO 97/27848	PCT				
	237	WO 97/38731	PCT				
	238	WO 97/45140	PCT				
	239	WO 98/45479	PCT				

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

240	Baselga et al., "Anti HER2 Humanized Monoclonal Antibody (MAB) Alone and in Combination with Chemotherapy Against Human Breast Carcinoma Xenografts" <u>Proceedings of ASCO-13th Annual Meeting</u> (Abstract #53), Dallas, TX 13:63 (Mar 1994)
241	Baselga et al., "Monoclonal antibodies directed against growth factor receptors enhance the efficacy of chemotherapeutic agents" <u>Annals of Oncology</u> (abstract #010) 5(Suppl. 5) (1994)
242	Guy et al., "Expression of the neu protooncogene in the mammary epithelium of transgenic mice induces metastatic disease" <u>Proc. Natl. Acad. Sci. USA</u> 89(22):10578-10582 (Nov 15, 1992)
243	"Herceptin (Trastuzumab)" <u>Product Information</u> (2000)
244	Hynes and Stern, "The biology of erbB-2/neu/HER-2 and its role in cancer" <u>Biochimica et Biophysica Acta</u> 1198(2-3):165-184 (Dec 30, 1994)
245	Mendelsohn et al., "Receptor blockade and chemotherapy: a new approach to combination cancer therapy" <u>Annals of Oncology</u> (abstract #040) 7(Suppl. 1):22 (1996)
246	Norton, L, "Evolving concepts in the systemic drug therapy of breast cancer" <u>Seminars in Oncology</u> 24(4 Suppl 10):S10-3-S10-10 (Aug 1997)
247	Ravdin and Chamness, "The c-erbB-2 proto-oncogene as a prognostic and predictive marker in breast cancer: a paradigm for the development of other macromolecular markers--a review" <u>Gene</u> 159(1):19-27 (Jun 14, 1995)

Examiner

Date Considered

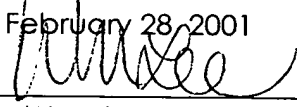
*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

TECH CENTER 1600/2900

JAN 21 2003

RECEIVED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Jeffrey L. Cleland et al. Serial No.: 09/273,230 Filed: March 18, 1999 For: PROTEIN FORMULATION	Group Art Unit: 1642 Examiner: G. Bansal CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on February 28, 2001  Wendy M. Lee
--	---

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR § 1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☐ **37 CFR § 1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR § 1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR § 1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR § 1.114.

☒ **37 CFR § 1.97(c)**

- by the applicant after the period specified in 37 CFR § 1.97(b), but prior to the mailing date of any of a final action under 37 CFR § 1.113, or a notice of allowance under 37 CFR § 1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR § 1.17(p) **or** a statement as specified in 37 CFR § 1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) **and** a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.

☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.

☒ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 08/615,369, filed March 14, 1996 and relied upon in this application for an earlier filing date under 35 USC §120.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-{}" (nucleotide) and "BLAST Results B-1 - B-{}" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the

Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR § 1.17(p).

Respectfully submitted,

GENENTECH, INC.

By: _____

Wendy M. Lee

Reg. No. 40,378

Telephone No. (650) 225-1994

Date: February 28, 2001




09157

PATENT TRADEMARK OFFICE

USCOMM-DC 80-398

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Jeffrey L. Cleland et al. Serial No.: 09/273,230 Filed: March 18, 1999 For: PROTEIN FORMULATION	Group Art Unit: 1642 Examiner: G. Bansal <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the "Express Mail Post Office to Addressee" service under 37 CFR 1.10 and is addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on Express Mail Label No.: EV 016 026 819 US <div style="text-align: center; margin-top: 10px;"> May 21, 2002  Wendy M. Lee </div> </div>
--	--

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
 Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

- ☒ **37 CFR §1.97(b)**
- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
 - within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
 - before the mailing of the first Office action on the merits; **or**
 - before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.
- ☐ **37 CFR §1.97(c)**
- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.

- ☐ **37 CFR §1.97(d)**

RECEIVED
 JAN 21 2003
 TECH CENTER 1600/2900

Serial No.: 09/273,230

Filed: March 18, 1999

Page 2

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified). A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 08/615,369, filed March 14, 1996 and relied upon in this application for an earlier filing date under 35 USC §120.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-0" (nucleotide) and "BLAST Results B-1 - B-0" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,

GENENTECH, INC.

By: 

Wendy M. Lee

Reg. No. 40,378

Telephone No. (650) 225-1994



09157

PATENT TRADEMARK OFFICE

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark OfficeAtty Docket No.
P0998D1Serial No.
09/273,230

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant
Cleland et al.Filing Date
18 Mar 1999Group
1642

U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date
253	4,714,759	22.12.87	Whitaker, Jr.			
254	4,816,567	28.03.89	Cabilly et al.			
255	4,861,579	29.08.89	Meyer et al.			
256	4,946,788	07.08.90	Delespesse			
257	4,962,035	09.10.90	Leder et al.			
258	5,091,313	25.02.92	Chang, T.			
259	5,231,026	27.07.93	Chang, T.			
260	5,252,467	12.10.93	Chang, T.			
261	5,254,671	19.10.93	Chang, T.			
262	5,260,416	09.11.93	Chang, T.			
263	5,274,075	28.12.93	Chang, T.			
264	5,292,867	08.03.94	Chang, T.			
265	5,342,924	30.08.94	Chang, T.			
266	5,362,643	08.11.94	Chang, T.			
267	5,420,251	30.05.95	Chang et al.			
268	5,422,258	06.06.95	Chang, T.			
269	5,428,133	11.12.91	Chang, T.			
270	5,654,403	05.08.97	Smith et al.			
271	5,792,838	11.08.98	Smith et al.			
272	5,942,210	24.08.99	Ultee et al.			
273	5,965,709	12.10.99	Presta et al.			
274	6,080,429	27.06.00	Cleland et al.			
275	6,267,958	31.07.01	Andya et al.			

RECEIVED
 JAN 21 2003
 TECH CENTER 1600/2900

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes No
276	171,496	19.02.86	EPO			
277	173,494	05.03.86	EPO			
278	184,187	11.06.86	EPO			
279	255,249	03.02.88	EPO			
280	263,655	13.04.88	EPO			
281	317,295	24.05.89	EPO			
282	589,840	30.03.94	EPO			
283	617,127	28.09.94	EPO			
284	648,499	19.04.95	EPO			
285	59-44399	12.03.84	JAPAN (TRANSLATION ATTACHED)			

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.

P0998D1

Serial No.

09/273,230

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Cleland et al.

Filing Date

18 Mar 1999

Group

1642

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Date	Country	Class	Subclass	Translation Yes	Translation No
	286 WO 86/01533	13.03.86	PCT				
	287 WO 89/04834	01.06.89	PCT				
	288 WO 89/06138	13.07.89	PCT				
	289 WO 91/11456	08.08.91	PCT				
	290 WO 93/04173	04.03.93	PCT				
	291 WO 93/19197	30.09.93	PCT				
	292 WO 95/15977	15.06.95	PCT				
	293 WO 97/04807	13.02.97	PCT				
	294 WO 97/10004	20.03.97	PCT				
	295 WO 97/33616	18.09.97	PCT				
	296 WO 99/01556	14.01.99	PCT				

RECEIVED
JAN 21 2003
TECH CENTER 1600/2900

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

- 297 Burton et al., "Lyophilized hyperimmune equine serum as a source of antibodies for neonatal foals" American Journal of Veterinary Research 42(2):308-310 (Feb 1981)
- 298 Cleland et al., "Development of Stable Protein Formulations for Microencapsulation in Biodegradable Polymers" Proceed. Intern. Symp. Control. Rel. Bioact. Mater. 22:514-515 (1995)
- 299 Natali et al., "Expression of the p185 encoded by HER2 oncogene in normal and transformed human tissues" International Journal of Cancer 45(3):457-461 (Mar 15, 1990)
- 300 Nitta et al., "Preliminary trial of specific targeting therapy against malignant glioma" Lancet 335(8686):368-371 (Feb 17, 1990)
- 301 Press et al., "Expression of the HER-2/neu proto-oncogene in normal human adult and fetal tissue" Oncogene 5:953-962 (1990)
- 302 Rensing et al., "The influence of sucrose, dextran, and hydroxypropyl-/142-cyclodextrin as lyoprotectants for a freeze-dried mouse IgG2a monoclonal antibody (MN12)" Pharmaceutical Research 9(2):266-270 (1992)
- 303 Valone et al., "Clinical trials of bispecific antibody MDX-210 in women with advanced breast or ovarian cancer that overexpresses HER-2/neu" Journal of Hematotherapy 4(5):471-475 (Oct 1995)

Examiner

Date Considered

*Examiner: Initial if reference considered; whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.